

## REMARKS

Entry of the above amendment is respectfully requested.

### Summary of Amendments

By the foregoing amendment, claims 2 and 15 are canceled, claims 39-48 are added and independent claims 1, 14 and 29 are amended, whereby claims 1, 3-14; 16-49 are pending in the present application. Claims 1, 14, 29 and 39 are independent claims.

Support for the new claims can be found throughout the present specification, for example, in the Examples thereof.

### Summary of Office Action

As an initial matter, Applicants note with appreciation that three signed and initialed copies of the Form PTO-1449 submitted in the Information Disclosure Statement filed October 20, 2003, the Supplemental Information Disclosure Statement filed January 6, 2004 and the Second Supplemental Information Disclosure Statement filed January 20, 2004 have been returned with the present Office Action. However, the present Office Action fails to acknowledge the claim of priority filed July 18, 2003. Accordingly, Applicants respectfully request that the claim for priority be acknowledged in the next communication from the Patent and Trademark Office.

Claims 29-38 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicants regards as the invention. Claim 29 includes three parenthetical expressions rendering the claims indefinite because it is unclear whether the limitations within the parentheses are meant to be part of the claimed invention.

Claims 1-38 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,904,534 to Nagai (hereafter "NAGAI") in view of Tomonaga et al. (U.S. Patent No. 4,222,128) (herafters "TOMONAGA") and in further view of EP 215 or IE 833.

Claims 1-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/615,013 in view of NAGAI.

**Response to Office Action**

Reconsideration and withdrawal of the rejections of record are respectfully requested in view of the foregoing amendments and the following remarks.

***Response to Rejection of Claims under 35 U.S.C. § 112***

In view of the Examiner's rejection of claims 29-38 under 35 U.S.C. § 112, second paragraph, because claim 29 contains three parenthetical expressions set forth in Paragraph 2 of the Office Action, Applicants amend Claim 29 by deleting the three parenthetical expressions so as to render this rejection moot. New claim 39 has been added and reveals these features and new dependent claims 40-48 correspond generally to claims 30-38.

In view of the foregoing, the rejection of claims 29-38 under 35 U.S.C. § 112 is

moot and withdrawal of this rejection is respectfully requested.

***Response to Rejection of Claims under 35 U.S.C. § 103(a)***

In view of the Examiner's rejection to claim 1-38 under 35 U.S.C. § 103(a) as being obvious over NAGAI in view of TOMONAGA, Applicants limit independent claim 1 by incorporating canceled claim 2, whereby claims 3-13 remain dependent, respectively, Applicants further limit independent claim 14 by incorporating canceled claim 15, whereby claims 16-28 remain dependent, Applicants further amend independent claim 29 by incorporating the same limiting phrase as in claim 14, whereby claims 30-38 remain dependent, and Applicants further limit newly added independent claim 39 by incorporating the same phrase as in claim 1, whereby claims 30-38 remain dependent.

In view of the foregoing, the incorporated limitations of independent claims 1, 14, 29 and 39 should overcome the Examiner's rejection.

Furthermore, in view of the Examiner's rejection to claim 1-38 under 35 U.S.C. § 103(a) as being obvious over NAGAI in view of Tomonaga and in view of EP 0962215 (hereafter EP'215) or IE 920 833 (hereafter IE'833), Applicants respectfully traverse the Examiner's rejection for the reasons discussed in detail below.

Amended claim 1 of the present application reads:

"A calcium phosphate-synthetic resin-metal composite body produced by pressing a metal member, a calcium phosphate block and a mixture of calcium phosphate particles, synthetic resin particles I, which are at least partially cross-linked in advance, and uncross-linked, synthetic resin particles II while heating, said calcium phosphate particles and/or said calcium phosphate block being exposed on at least part of the surface of said composite body, wherein said synthetic resin particles I and II are bonded to said metal member, said calcium phosphate particles and said calcium phosphate block. (emphasis

added)"

It is novel that

- (1) the calcium phosphate-synthetic resin composite body is produced by pressing a calcium phosphate block, calcium phosphate particles and synthetic resin particles I, which are at least partially cross-linked in advance, and uncross-linked, synthetic particles II while heating in the state where the calcium phosphate block is exposed on at least part of the surface of the composite body, and
- (2) the synthetic resin particles I and II are bonded to the metal member, the calcium phosphate particles and the calcium phosphate block.

Thus, the independent claims recite novel and non-obvious subject matter in view of failure of the art to disclose or suggest these features. New dependent claim 49 is also non-obvious and even further recites that

- (3) the synthetic resin particles I are softened while retaining their shapes to some extent, whereas the uncross-linked, synthetic resin particles II having thermoplasticity are softened or melted during pressing while heating (emphasis added) (see also and also page 3, lines 21-25 of the specification).

As a result, the metal member and calcium phosphate particles and a calcium phosphate block are firmly fixed in the composite body by bonding the synthetic resin particles to the metal member, the calcium phosphate particles and the calcium phosphate block, and accordingly, at the time of cutting and polishing, exfoliation occurs at interfaces between the calcium phosphate particles and the synthetic resin and at the

interfaces between the synthetic resin particles I and II, so that the calcium phosphate-synthetic resin composite body containing the calcium phosphate particles has excellent workability (see page 4, lines 9-16 in view of page 3, line 27 to page 4, line 5 of the description), and moreover, a calcium phosphate-synthetic resin composite layer particularly excellent in biocompatibility covers the entire surface of the metal member (see page 4, lines 17-21 of the description).

In contrast to the claimed invention, NAGAI discloses an implant material excellent in the adhesion to a metallic material, mechanical properties, stability in the living body and osteogenesity, whereby the implant material being produced by forming a layer of a thermosetting resin, which has excellent stability in a living body and biocompatibility, around the metallic material or a layer of composition comprising the thermosetting resin (from, less than 1000 micrometers in diameter around the outer surface of the metallic material (e.g., stainless steel, titanium, etc.) (emphasis added) (see column 2, lines 44-61; column 3, lines 27-31 and lines 32-39 of NAGAI).

However, NAGAI is silent as to the use of a thermoplastic resin in the layer composition and also fails to teach or suggest any feature such that the synthetic resin particles I, which are at least partially cross-linked in advance, and uncross-linked, synthetic resin particles II are bonded to the metal member, the calcium phosphate particles and the calcium phosphate block.

Therefore, one of ordinary skill in the art, referring to NAGAI, which does not teach or suggest at least one of the features of the claimed invention mentioned above, would not be motivated to arrive at the invention of claim 1, and, accordingly, claim 1 of the

present application would not have been obvious over NAGAI.

Also, TOMONAGA discloses a composite implant material comprising a sintered apatite material and a thermoplastic or thermosetting resin, which is prepared by forming a sintered apatite material and filling or impregnating a thermoplastic or thermosetting resin into the pores or holes of the sintered material, which have been formed during the formation of the sintered material or perforated after the formation thereof. The composite implant material has controlled compatibility to bone as well as excellent physical strength. (emphasis added) (see abstract)

TOMONAGA merely discloses a composite implant material comprising a sintered apatite material and a thermoplastic or thermosetting resin, at least said sintered apatite material existing in a continuous phase and the respective phases of said sintered material and said thermoplastic or thermosetting resin being exposed, in part, to the surface of said implant material (see column 1, lines 53-61 of TOMONAGA).

In the present invention, the synthetic resin particles I are softened while retaining their shapes, whereas the uncross-linked, synthetic resin particles II having thermoplasticity are softened or melted during pressing while heating (emphasis added) (see page 3, lines 21-25 of the description), thereby making it possible to firmly fix the metal member and calcium phophate particles and a calcium phosphate block in the composite body by bonding the synthetic resin particles to the metal member, the calcium phosphate particles and the calcium phosphate block, and accordingly, the calcium phosphate-synthetic resin composite body containing the calcium phosphate particles has excellent workability, and moreover, a calcium phosphate-synthetic resin composite

layer particularly excellent in biocompatibility covers the entire surface of the metal member.

In contrast to the above, TOMONAGA teaches that the thermoplastic or thermosetting resin may be directly impregnated into the pores of the sintered material (see column 2, lines 53-56 of TOMONAGA), and, accordingly, the resin should be presumably used in a liquid state thereof. (emphasis added)

A thermosetting resin is originally liquid, and the thermosetting resin is cured by heating in the presence of a curing agent as described in TOMONAGA (see column 4, lines 12-26 of TOMONAGA). Also, with respect to a thermoplastic resin, even though it has a particle shape, the particle shape thereof may not be retained by melting thereof while heating,

Accordingly, the composite implant material of TOMONAGA does not have interfaces between the resin particles, while the resin particles used are integrated, thereby allowing the implant material to have poor workability compared to the calcium phosphate-synthetic resin composite body of the present application.

In addition, TOMONAGA is silent regarding the simultaneous use of both, a thermoplastic and a thermosetting resin.

Therefore, someone skilled in the art referring to TOMONAGA, which does not teach or suggest at least one of the major distinguished features (1), (2) and (3) of the claimed invention, would not be motivated to reach the invention of the amended claim 1, and, accordingly, the amended claim 1 of the present application is not obvious over TOMONAGA.

Further, EP'215 discloses a dental composition comprising

- (A) at least one monomer and/or oligomer in an amount of 20-50 wt% selected from methacrylates and acrylates,
- (B) an uncrosslinked polymer in an amount of 5-70 wt% selected from homopolymers of methacrylates, acrylates and styrene; copolymers of at least two monomers selected from methacrylates, acrylates and styrene; mixtures of the homopolymers; mixtures of the copolymers; and mixture of the homopolymer(s) and the copolymer(s), the uncrosslinked polymer having an average particle size of 100  $\mu\text{m}$  or less,
- (C) a crosslinked polymer in an amount of 1-60 wt% selected from homopolymers of methacrylates, acrylates, and styrene; copolymers of at least two monomers selected from methacrylates, acrylates, and styrene; mixtures of the homopolymers; mixtures of the copolymers; and mixtures of the homopolymer(s) and copolymer(s), the crosslinked polymers having an average particle size of 100  $\mu\text{m}$  or less,
- (D) an organic and inorganic filler complex in an amount of 1-65 wt%, which has an average particle size of 1-50  $\mu\text{m}$  and is obtained by mixing the inorganic filler (e.g., silica powders) mentioned below with methacrylate or acrylate monomer, polymerizing and pulverizing them, and optionally
- (E) an inorganic filler having an average particle size of 0.005-50  $\mu\text{m}$ . (see Abstract; paragraph Nos. [0010], [0029], [0032], [0033], [0035] and [0049] of EP'215)

However, EP'215 fails to teach or suggest any feature such that uncross-linked polymer particles and cross-linked polymer particles are bonded to the metal member,

the calcium phosphate particles and the calcium phosphate block.

Therefore, one of ordinary skill in the art referring to EP'215, which is silent regarding the features of the claimed invention as mentioned above would not be motivated to arrive at the invention of claim 14, and accordingly, claim 14 of the present application is not obvious over EP'215.

Furthermore, IE'833 discloses dental materials containing

- a) 5 to 30 part by weight of an organic filler consisting of polymeric crosslinked (meth)acrylates having a particle size in the range from 0.001 to 100  $\mu\text{m}$ , a degree of swelling of 50 to 2000% by weight and a degree of crosslinking of 1 to 100% by weight, in each case based on the polymer,
- b) 40 to 80 parts by weight of (meth)acrylates, which can form crosslinkings,
- c) 0 to 40 parts by weight of (meth)acrylates, which cannot form crosslinkings,
- d) 10 to 40 parts by weight of a silanised inorganic filler (e.g., stabilizers, pigments, etc.) (see claim 1; page 3, lines 2-16; page 28, lines 20-25; and page 29, lines 23-26 of IE'833).

However, IE'833 fails to teach or suggest any feature such that the uncross-linked polymer particles and cross-linked polymer particles are bonded to the metal member, the calcium phosphate particles and the calcium phosphate block.

Therefore, those of ordinary skill in the art referring to IE'833, which is silent regarding the features of the claimed invention as mentioned above would not be motivated to arrive at the invention, and accordingly, the invention of claim 1 of the present application is not obvious over IE'833.

With respect to claims 3-13 of the present application, the patentability of these claims is also clear at least by virtue of their dependence of the amended claim 1.

Amended claim 14 of the present application reads:

"A calcium phosphate-synthetic resin-metal composite body produced by pressing a metal member and a mixture of calcium phosphate particles, synthetic resin particles I, which are at least partially cross-linked in advance, and uncross-linked, synthetic resin particles II while heating, said calcium phosphate particles being exposed on at least part of the surface of said composite body, wherein said synthetic resin particles I and II are bonded to said metal member, said calcium phosphate particles and said calcium phosphate block."

Claims 1 formulates a product-by-process claim of a composition comprising a metal member, a calcium phosphate block and a mixture of calcium phosphate particles, synthetic resin particles I, which are at least partially cross-linked in advance, and uncross-linked, synthetic resin particles II while heating, whereas the latter formulates a composition comprising a metal member, calcium phosphate particles, synthetic resin particles I, which are at least partially cross-linked in advance, and uncross-linked, synthetic resin particles II while heating.

Thus, it is seen that the synthetic resin particles I and II, which are bonded to the metal member and the calcium phosphate particles except for the calcium block, whereby not only the calcium phosphate particles are firmly fixed by the synthetic resin particles I and II, but also the synthetic resin particles I and II are firmly bonded to each other, so that the calcium phosphate-synthetic resin composite body containing the calcium phosphate particles has excellent workability, and, moreover, a calcium phosphate-synthetic resin composite layer particularly excellent in biocompatibility covers

the entire surface of the metal member. (see page 4, lines 14-26 in view of page 2, line 21 to page 4, line 4 of the present description)

Therefore, none of NAGAI, TOMONAGA, EP'215, IE'833, taken alone or even in any combination, teaches or suggests the major distinguished feature (2) of the present invention of claim 14, and, accordingly, claim 14 of the present application is not obvious over NAGAI in view of TOMONAGA and in further view of EP'215 or IE'833.

With respect to claims 16-28 of the present application, their patentability is also clear by virtue of their dependence of the amended claim 14.

The amended claim 29 of the present application calls for a method of producing a calcium phosphate-synthetic resin-metal composite body of claim 14, and, accordingly its patentability is clear for the reasons mentioned above.

With respect to claims 30-38, their patentability is clear at least by virtue of the basis of their dependence of the amended claim 29.

Also, new claim 39 recites a method for producing a calcium phosphate-synthetic resin-metal composite body of claim 1, and accordingly its patentability is clear for the reasons mentioned above in the paragraphs discussing the patentability of amended claim 1.

With respect to new claims 40-48, their patentability is clear at least by virtue of the basis of their dependence of the amended claim 39.

***Response to Double Patenting Rejection***

With respect to the Examiner's rejection to claims 1-38 based on the obviousness-type double patenting over claims 1-24 of copending Application No. 10/615,013 in view of NAGAI set forth in the Office Action, Applicants submit herewith a Terminal Disclaimer. Therefore, it is believed that this rejection is moot and should be withdrawn.

**CONCLUSION**

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,  
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